REMARKS

Claims 33, 35-38, 47-50 and 53 are pending in this application.

Claims 33, 36, 37, 38, 47 and 50 have been amended.

Claims 1- 32, 34, 39-46, 51 and 52 have been cancelled.

Claim 53 is new and is based on the previous version of claim 33.

The explanation of the amendments is summarized below:

Previous claims	Amended New Claims	Changes made
33	----	amended
34	----	Claim cancelled
35	----	Claim unchanged
36	----	Claim currently amended and the phrase "cephalosporins" has been deleted
37	----	Claim currently amended The phrases "hydroxypropylmethyl cellulose acetate succinate", "cellulose acetate phthalate", "cellulose acetate butyrate", "cellulose acetate propionate", "alginates" and "chitosans" have been deleted
38	----	Claim currently amended The phrase "hydroxypropylmethyl cellulose acetate succinate", "cellulose acetate butyrate" and "cellulose acetate propionate" have been deleted
39-46	----	Claims cancelled
47	----	Claim currently amended and made dependent on claim 33
48-49	----	Claims withdrawn
50	----	Claim withdrawn and the phrase "cephalosporins" has been deleted
51-52	----	Claims cancelled

The Examiner has issued an Official Action requiring restriction between two groups of inventions. The groups identified by the Examiner are:

> Group I: Claims 33-47 drawn to a rapidly disintegrating oral controlled release pharmaceutical composition comprising at least one active ingredient and a polymer system comprising at least two polymers and
>
> Group II: Claims 48-52 drawn to a process for preparing a rapidly disintegrating oral controlled release pharmaceutical composition comprising at least one active ingredient, and polymer system comprising at least two polymers.

Applicants respectfully traverse this restriction requirement.

On page 2 of the Official Action, the Examiner states that the species lack the same or corresponding special technical features because the common technical feature is the rapidly disintegrating oral controlled release pharmaceutical composition of claim 33. The Examiner states that '[t]his element cannot be a special technical feature under PCT Rule 13.2 because it is not novel." and the Examiner states that "Lorenzo-Lamosa et al. (Journal of Controlled Release, 1998) discloses a peroral pharmaceutical composition (a rapidly disintegrating oral controlled release pharmaceutical composition) with colonic drug delivery." Applicants respectfully disagree with the Examiner's statement that the composition and process claims are not novel. Lorenzo-Lamosa M L et al. primarily describes a new colonic drug delivery system consisting of chitosan core-coated microspheres, which have the special feature of releasing the encapsulated drug at pH 7.4 continuously over prolonged and adjustable period of time. The system described consists of chitosan microcores entrapped within acrylic microspheres. Sodium diclofenac used as a model drug, was efficiently entrapped within chitosan microcores using spray-drying and then microencapsulated into Eudragit L-100 and Eudragit S-100 using an oil-in-oil solvent evaporation method. The Lorenzo-Lamosa paper describes release of the active ingredient specifically in the colonic environment (refer page 110, column 2 of the cited literature document). The claimed invention does not involve the formation of chitosan microcores entrapped within acrylic microspheres. The claimed invention relates to controlled release mucoadhesive rapidly disintegrating type compositions which disintegrate into particles that have increased residence time in the stomach. For example, in the composition of claim 3 the antibiotic is released in the stomach or upper part of the intestine and maintaining concentrations above effective levels for extended periods of time.

The feature of the active ingredient being released in the stomach or upper part of the intestine and maintaining concentrations above effective levels for extended periods of time is disclosed and discussed on page 5, line 16-page 6, line 7 and page 8, lines 10-15 of the specification.

Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 31 USPQ 1671 (Fed. Cir. 1994). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

As explained above, it is clear that each element of the claims is not disclosed in Lorenzo-Lamosa so the claims are novel in view of this reference.

Furthermore, there is no disclosure, suggestion, teaching or motivation in Lorenzo-Lamosa to use a combination of polymers comprising an acid insoluble polymer such as methacrylic acid polymer (Eudragit) and bioadhesive polymer such as Polycarbophil which retard the release in the stomach while providing rapid dissolution in the alkaline contents of small intestine. Hence, just by mere disclosure of conventional excipients one skilled in art cannot formulate rapidly disintegrating, mucoadhesive, modified release compositions comprising an active ingredient such as penicillin antibiotic(s) and by using a combination of polymers (acid insoluble polymer such as methacrylic acid polymer and bioadhesive polymer such as polycarbophil). Thus, the claimed invention is patentable over this paper.

Based on this, it is respectfully requested that the restriction requirement be withdrawn.

However, if the Examiner maintains the requirement, the claims of Group I claims 33-47 are provisionally elected.

All rights to file one or more divisional applications directed to the subject matter of the nonelected claims and/or any other subject matter disclosed in the specification are preserved.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

/Janet I. Cord/

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